



# HUMAN CLONING AND FDA REGULATION

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HUMAN CLONING  
AND FDA REGULATION

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## I.

### INTRODUCTION

In the February 27, 1997 issue of the journal *Nature* scientists from Scotland's Roslin Institute reported their successful efforts to clone an adult sheep using differentiated somatic cells from the animal. The clone, named Dolly, was the first instance of the successful cloning of an adult mammal. The shock waves created by the possible ramifications of this development were immediately felt around the world. For the first time, the cloning of an adult human being was no longer being considered an impossibility in mainstream scientific circles. Scientists, governments and laymen around the world were now forced to begin considering the consequences of utilizing this new technology to clone adult human beings.

Prior to the announcement by Dr. Richard Seed that he would begin using this technology as an alternative for infertile couples, a temporary moratorium on any attempts to clone an adult human being was proposed. While such a moratorium is generally accepted by most groups, further consensus on how these activities should be treated remains elusive. Legal, religious, moral and scientific considerations are intertwined with a complexity found in few other areas of public concern. Created hastily, most state and federal legislative proposals are criticized as being overly broad and based on uninformed analysis.

In an attempt to develop a more reasoned approach, many in industry

and academia alike have proposed that regulation of these activities be put in the hands of some federal agency with more experience in these matters. Early on in the debate, the Food and Drug Administration (FDA) announced that under already proposed guidelines it had authority to regulate in this area. Whether as a temporary or permanent solution, FDA regulation of human cloning was widely viewed as a moderate and appropriate alternative to pursue. Despite persistent efforts though, no permanent resolution of this debate has yet been achieved.

In this paper I will first describe the science behind this new technique of cloning, both the methods employed in the process and the resulting uses of the technology. In part three, I will briefly elucidate the major elements in the debate over how to treat this technology so that we will be able to judge whether the solutions proposed deal with the concerns mentioned. Part four deals with the various governmental responses to the use and development of these techniques. Part five discusses the FDA's role in regulating this new technology. This latter section includes a description and analysis of the current proposal for FDA regulation in this area as well as a model for future legislation meant to improve upon the current regulatory regime.

## **II.**

### **THE SCIENCE OF CLONING**

#### **A.**

## METHODS OF CLONING

Cloning is a technology which has been in use for quite some time. In agricultural applications it is quite common and “at the molecular and cellular level, scientists have been cloning human and animal cells and genes for several decades.”<sup>1</sup> In general there are three basic types of cloning; molecular (or gene) and cellular cloning which are not capable of developing into offspring and a third type which is geared towards reproducing genetically identical animals.<sup>2</sup> The first two types of cloning are the backbone of modern biotechnology and have proven invaluable in the fields of healthcare and medicine. In addition to resulting in the development of new vaccines and processes for the production of insulin, these technologies have made gene therapy and the mapping of the human genome a reality.<sup>3</sup> Since they are not capable of producing offspring however they are only tangentially of concern here.

The third type of cloning can be broken down into two distinct processes; “blastomere separation” and “nuclear transplantation cloning”.<sup>4</sup> Blastomere separation involves the separation of embryonic cells, known as blastomeres, for use in producing multiple organisms which are genetically identical. Each blastomere is an undifferentiated cell and is totipotent. Totipotency indicates that each cell has the “total potential” to create an entire organism. The cells

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<sup>1</sup> *Cloning Human Beings*, Report and Recommendations of the National Bioethics Advisory Commission (NBAC Report), pg. 14, June 1997.

<sup>2</sup> *Id.*

<sup>3</sup> See, e.g., William S. Klug, *Essentials of Genetics* 375-383 (1996); T.A. Brown, *Gene Cloning* 246-267 (1990)

<sup>4</sup> NBAC Report, pg. 14

are separated soon after fertilization when the embryo consists of only two to eight cells and then implanted into the uterus of separate surrogate “parents” and allowed to develop normally in the womb. This form of cloning has great relevance for the livestock breeding industry and is not a cause of the current controversy.

Nuclear transplantation cloning is the most sophisticated cloning technique. It involves removing the nucleus from an egg and replacing it with a nucleus taken from another cell. Once implanted in the egg, the embryo is allowed to develop along its natural course. The offspring thereby created is a genetic “twin” of the donor animal. Until recently, scientists believed that only embryonic cells before reaching a certain stage of maturity could be utilized as donor cells in this process. This is because it was believed that once the embryonic cells began to differentiate and become specialized, that is become cells of specific types of tissue, they lost their totipotency. What the scientists who created Dolly demonstrated was that the nucleus of a differentiated adult mammalian somatic cell could be reprogrammed and used in this process. In other words, cell differentiation and specialization can be reversed in the somatic cell of an adult mammal and a genetic twin of that animal can be created from that cell. The process used is known as somatic cell nuclear transplantation (SCNT). Of course the clone would still have to go through the normal stages of development of its species so the two animals would not be present in the same stage of development at any time, but for the first time it is possible to create a mammalian organism which is genetically identical to a pre-existing

adult organism from the genetic material contained in a somatic cell of the adult organism. This latter point is where the revolution lies.

In short, the procedure used by the scientists at the Roslin Institute began by extracting a cell from an adult sheep's udder and then removing the nucleus from the egg of another sheep. The donor sheep's cell nucleus and the egg were then fused by exposure to an electrical current which also resulted in activating the process of division within the new cell. The developing embryo was then implanted within the womb of a third sheep and left to develop normally. A major drawback of the scientists technique was that only 1 of 277 of their attempts at this process developed into a live lamb. This and the fact that the method utilized had not allowed for absolute verification that the donor cell used was a fully differentiated cell, made some scientists wonder if perhaps a less than fully differentiated cell had been used in the experiment and thus that the results were not as revolutionary as was being claimed.

Any doubts as to the possibility of cloning an adult mammal via the method of nuclear transplantation was put to rest July 22, 1998 by a report out of the University of Hawaii. Researchers there had documented proof that they had not only successfully cloned adult mice, but that they had made clones of the clones.<sup>5</sup> These researchers reported that they had produced more than 50 identical cloned mice.<sup>6</sup> They also noted a higher success rate than that achieved by the scientists at the Roslin institute (about 3%).<sup>7</sup> and attributed it to the

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<sup>5</sup>University of Hawaii, *UH News* (press release date July 22, 1998)  
<[http://www.hawaii.edu/ur/News\\_Releases?NR\\_July98/cloning.html](http://www.hawaii.edu/ur/News_Releases?NR_July98/cloning.html)>

<sup>6</sup>*Id.*

<sup>7</sup>*Id.*



fact that they utilized a slightly different technique which consisted of injecting the nuclei from the cell of a donor mouse into the enucleated egg where division was jump started using chemical, as opposed to electrical, processes with the result then being implanted into the uterus of a surrogate “parent” for normal fetal development.<sup>8</sup>

The experiments above indicate that there is nothing from a scientific standpoint which would stop the cloning of an adult human being. Early questions focused on the fact that embryonic gene activation in sheep occurs later than it does in humans and thus timing might be a limiting factor in the cloning of humans. The concurrent period in mice however is much shorter than in humans so from the University of Hawaii study it appears that timing may not inhibit efforts as much as had been speculated. If we can clone an adult human being then, the question becomes one of the uses undertaking such an activity could be put to.

B.

#### USES OF SCNT HUMAN CLONING TECHNOLOGY

As indicated above, nuclear transplant technology is not synonymous with human cloning, but is merely a technique which may be used to accomplish the latter. Short of actually cloning human beings, this technology holds great promise for the medical and biotechnology industries as well as for the produc-

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<sup>8</sup>*Id.*

tion of livestock. “Work with [nuclear transplantation technology] is already providing unparalleled insights into fundamental biological processes and promises to provide great practical benefit in terms of improved livestock, improved means of producing pharmaceutical proteins, and prospects for regeneration and repair of human tissues.”<sup>9</sup>

Notwithstanding the tremendous possibilities engendered by this new technology in other areas though, we still need to examine the benefits, if any, related to the cloning of adult human beings by SCNT. The most often cited and morally defensible application for this technology is in infertility programs. In a variety of situations, these techniques may allow couples previously unable to bare children to have children genetically related to the donor parent. Also, for couples whose families carry a genetic disposition towards certain illnesses or disabilities, the cloning of a healthy parent can allow for the birth of a healthy child without the concurrent risks of developing the feared genetically induced abnormalities. These and an assortment of other similar situations could result in SCNT delivering great benefits to families seeking to have children.

Beyond the aforementioned uses however, in and of themselves controversial in some circles, the questions of moral defensibility of our actions become more difficult to satisfy. Certain individuals have suggested programs or procedures for cloning humans in order to harvest the clone’s organs for transplantation into genetically compatible non-clones. This practice could essentially eliminate the possibility of organ rejection by the immune system of an organ recipient and

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<sup>9</sup>NBAC Report, pg. 34

also solve the current shortage of available organs for transplantation. Others have imagined eugenic programs designed to eliminate or reduce the incidence of some genetically induced disabilities. As described by its proponents, this proposal is similar in spirit and practice to that described above involving parents wishing to have a healthy child. The benefits and harms of both courses of action can be easily imagined.

Despite the concerns which may be raised by the above applications, any work carried out in the field of human cloning will shed great light on the processes of human development and the role genetics plays in this development. Thus, from a purely scientific standpoint, the new insights gained into the very nature of life itself may be invaluable. This new knowledge, in turn, is likely to lead to a new understanding of diseases and disabilities of many kinds and perhaps also their cures. It may then be possible to control, if not eradicate altogether, many of the health concerns which currently occupy the human species. Any program which may result in the amelioration of human pain and suffering carries with it obvious benefits and thus its implementation cannot be dismissed out of hand. Given the uses and benefits herein described, the next question which must be considered is whether the cloning of human beings via SCNT technology should be undertaken.

### **III.**

## **THE DEBATE OVER HUMAN CLONING AND SCNT TECHNOLOGY**

The debate over human cloning by application of SCNT technology is taking place on many fronts. The consensus among scientists is that current methods for cloning human beings using this technology pose too great a risk to the developing clone to justify attempting to carry out such a feat. Until more reliable procedures are developed, human cloning by these means will result in babies born with severe genetic abnormalities. The hazards to the developing fetus are demonstrated by the low success rate of the above experiments and the fact that the researchers who created Dolly also “generated dozens of fetuses with severe malformations.”<sup>10</sup> Thus, the scientific community seems to favor a temporary moratorium on such activities until such time as they can be demonstrated to be reasonably benign.

In legal circles, much of the debate revolves around the idea of the act of procreation as a constitutional right.<sup>11</sup> This “right” was given rather expansive treatment by the court for the Northern District of Illinois when it stated that “within the cluster of constitutionally protected choices [is] the right to submit to a medical procedure that may bring about...pregnancy” including the decision to undergo in vitro fertilization using donated embryos.<sup>12</sup> According to University of Texas Law Professor John Robertson “[I]f procreative liberty is taken seriously, a strong presumption in favor of using technologies that cen-

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<sup>10</sup>Katheryn D. Katz, *The Clonal Child: Procreative Liberty and Asexual Reproduction*, 8 Alb. L.J. Sci. & Tech. 1, 28 (1997)

<sup>11</sup>*See, e.g., Griswold v. Connecticut*, 381 U.S. 379 (1965) (the right whether to bear children is protected under the constitutional right to privacy); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (the right whether to bear children is protected under the constitutional right to privacy)

<sup>12</sup>*Lifchez v. Hartigan*, 735 F.Supp. 1361, 1377 (N.D. Ill. 1990), *aff’d without opinion, sub nom., Scholberg v. Lifchez*, 914 F.2d 260 (7<sup>th</sup> Cir. 1990), *cert. denied*, 111 S.Ct. 787 (1991).

trally implicate reproductive interests should be recognized. Although procreative rights are not absolute, those who would limit procreative choice should have the burden of establishing substantial harm.”<sup>13</sup> This, he argues, is the traditional analysis engaged in in decisions regarding procreational freedoms.<sup>14</sup> Robertson has gone on to argue that cloning specifically should be included in our bundle of procreative liberties because it is so similar to current forms of reproduction and family formation that it should be treated equivalently.<sup>15</sup> Thus, lacking some “substantial harm,” it would seem that legal principles indicate a permissive attitude towards the use of this new technology for cloning humans, at least in the context of child rearing.

The moral/ethical arguments seem focused in three general areas. The first two deal with the affects of cloning on, and the well being of, the clones themselves while the third deals with the overall effect on society that carrying out this activity en mass would have. The initial area of concern regards the treatment of clones as objects as opposed to as human beings. It is feared by some that if people are allowed to produce clones at will, the resulting offspring will be treated as possessions or objects instead of as living beings in possession of basic human rights. This argument is especially relevant when the subject of harvesting clones for their organs is discussed. The counter to this argument is that individuals currently can have children at will and are more or less charged with the responsibility to raise them as children. Still, the ability to create a

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<sup>13</sup>John A. Robertson, *Children of Choice: Freedom and the New Reproductive Technologies* 40-41 (1994).

<sup>14</sup>*Id.*

<sup>15</sup>John A. Robertson, *Liberty, Identity, and Human Cloning*, 76 Tex. L. Rev. 1371, 1394 (1998)

human being for the specific purpose of transplantation of their organs raises serious questions about the liberty and well being of the person so created.

The next area of concern revolves around the attainment of an individual identity by a clone. When the genetic make-up of a particular human being can be reproduced exactly in ones offspring, there are questions as to whether society or the clone herself will ever think of the clone as a unique individual. The argument is made that given the outcome of the life of the individual donor that the clone was based on, there will be a set of expectations as to what the clone is capable of and indeed may eventually become. This set of expectations, it is feared, may preclude the development of an independent self in the clone. The strength of this argument is that it is based upon perception and not reality. That is, although strict genetic determinism does not govern the type of individual a person will become, the perception in peoples minds often does not correspond to reality and may in fact contradict it, thus resulting in the situation feared.

The final scenario involves the use of eugenics to create some kind of a “master race.” While we all can agree that the elimination of human suffering through genetic engineering is a laudable goal, we must be careful as to how far we are willing to go in “perfecting” our species. For instance, at what point does an undesirable characteristic, such as being short, become a disability which we would choose to eradicate. While it is easy to favor the elimination of diabetes, where do we stop? How do we choose who is to be cloned and can we permit ourselves to grant this freedom to some and not others? Moreover, when at-

tempting to clone true for certain intangible characteristics such as intelligence, we will become the slaves of our necessarily imperfect definitions. Disappointment will also follow when those who aren't aware discover that environmental conditions throw a monkey wrench into the gears of genetic determinism and that what they sought is not inevitably what they get.

Finally, in the area of religion, the argument most often put forth is that man is putting himself in the sphere of God. It has been argued that by choosing to create life in this manner, man is somehow committing a grave and dangerous "sin". In this milieu, mans hubris is evidenced by his will to create human life by "artificial" means, and must be avoided by refusing the opportunity presented to us. According to Gilbert Meilander, it is part of man's essential nature in God's plan to be "begotten, not made."<sup>16</sup> The counter to this argument is that by practicing this new technology we are merely utilizing the tools that God has given us by ordering nature in the manner that he has chosen. In so doing, we exercise our rightful dominion over the Earth and its creatures, granted to man by God in Genesis.<sup>17</sup>

This brief discussion certainly does not sum up all the arguments in the debate, but it does give a good overview of those arguments most often enunciated. While I do not offer an answer to any of these questions, they are presented so that we may evaluate the proposal for FDA regulation of human cloning given below. It will be important that any proposed regulation or legislation address

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<sup>16</sup>Gilbert Meilander, Remarks on human cloning to the National Bioethics Advisory Commission, March 13, 1997.

<sup>17</sup>*Genesis* 1:28 (New International Version Study Bible), "God blessed them and said to them... fill the earth and *subdue* it. *Rule over...* every living creature that moves...."

the concerns of a vast cross section of the American public. As a result, we will be revisiting these issues in the discussion which follows.

#### IV.

### GOVERNMENTAL RESPONSE

In anticipation of the report of Dolly to be published in *Nature*, President Clinton, on February 24, 1997, issued a directive to the National Bioethics Advisory Commission (NBAC). In this directive the President requested that the NBAC conduct a “thorough review of the legal and ethical issues associated with the use of this technology” and make “recommendations on possible federal actions to prevent it’s abuse.”<sup>18</sup> A week later the President barred the use of federal funds for any research leading to the cloning of human beings until there was time to complete a review of its ethical implications.<sup>19</sup> In the same address, Clinton “asked for a voluntary moratorium on the cloning of human beings” to be adhered to by the private sector.<sup>20</sup>

The NBAC released it’s report June 6, 1997. In the report, the NBAC concluded that “at this time it is morally unacceptable for anyone to attempt to create a child using somatic cell nuclear transfer cloning...because...information

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<sup>18</sup>*Clinton Seeks Legal, Ethics Review of Issues Related to Human Cloning*, BNA Chem. Reg. Daily (Bur. of Nat’l. Affairs Inc.) February 26, 1997.

<sup>19</sup>*Clinton Bars Federal Funding for Human Cloning; Seeks Voluntary Halt*, BNA Chem. Reg. Daily (Bur. of Nat’l. Affairs Inc.) March 6, 1997.

<sup>20</sup>*Id.*



indicates [it] is not safe to use in humans at this time.”<sup>21</sup> Based on this and other findings the commission recommended:

1. “[C]ontinuation of the current moratorium on the use of federal funding in support of any attempt to create a child by somatic cell nuclear transfer.”
2. A request be made for voluntary compliance with the moratorium by all non-federally funded research and commercial interests.
3. “Federal legislation should be enacted to prohibit anyone from attempting...to create a child through somatic cell nuclear transfer cloning...[but that] such legislation include a sunset clause.”
4. “Any regulatory or legislative action undertaken to effect the foregoing prohibition...should be carefully written so as not to interfere with other important areas of scientific research.”
5. If a ban is not enacted, or is ever lifted, clinical use of SCNT techniques should be preceded by research trials governed by accepted protocols.
6. The U.S. should cooperate with other international efforts to regulate human cloning.
7. Widespread and continuing deliberations on the issues involved should be carried out as well as an effort to educate the lay public in the areas of genetics and other biomedical sciences.<sup>22</sup>

Three days after the release of the commissions report, Clinton proposed the Cloning Prohibition Act of 1997. The Act was designed to have the effect of prohibiting for five years the use of SCNT technology for the purpose of cloning a human being. In order to insure that the Act didn’t interfere with beneficial biomedical and agricultural activities, Clinton stressed that “this legislation...will not prohibit the use of [nuclear transplantation technology] to clone DNA cells, and it will not ban the cloning of animals.”<sup>23</sup> Despite administration efforts, the proposed legislation was never acted upon.

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<sup>21</sup>NBAC Report pg. 108.

<sup>22</sup>*Id.* at 109-110.

<sup>23</sup>*Clinton Proposes 5-Year Ban on Human Cloning*, BNA Washington Insider (Bur. of Nat’l. Affairs Inc.) June 10, 1997.

Before Clinton proposed his legislation on human cloning, 16 bills were introduced in 12 different state legislatures.<sup>24</sup> One bill banned the use of government funds for any research using cloned cells or tissues, two banned the use of government funds for cloning a complete human being, nine banned the cloning of a human being regardless of whether funding was public or private, two banned any research using cloned cells or tissue while two others could have had the effect of unintentionally banning research using cloned cells or tissue.<sup>25</sup> It is clear that this patchwork of state legislation would not have created a consistent regime for researchers and biotech companies to operate in. In fact, some of the legislation prohibited practices already well established and accepted. If these laws were to go into effect, many of the current medical techniques health care workers and the public depend on would be forbidden.

One of the first federal congressional proposals was H.R. 922, introduced by Rep. Vernon Ehlers (R-Mich.) on March 15, 1997. The purpose of this bill and its companion H.R. 923, also proposed by Ehlers, is to prohibit the use of federal funds to conduct or support research on the cloning of humans using SCNT technology. While H.R. 922 was approved by the House Science committee in July of 1997, it is still under consideration by the House Com-

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<sup>24</sup>*States with bills pending:* banning the use of government funds for any research using cloned cells or tissues: *Alabama* (A.B. 1082); banning the use of government funds for cloning a complete human being: *Missouri* (1997 Mo. H.B. 824), *Maryland* (Md. H.J.R. 28); banning the cloning of a human being regardless of whether funding was public or private: *Alabama* (S.B. 511), *California* (Cal. S.B. 1344), *Illinois* (1997 Ill. H.B. 2235 ♣ 5 and 1997 Ill. S.B. 1829), *New Jersey* (N.J.A.B. 2849 ♣ 1), *New York* (1997 S.B. 2877), *North Carolina* (S.B. 782), *Oregon* (Ore. S.B. 1017 ♣ 1) *West Virginia* (W.Va. S.B. 410); banning any research using cloned cells or tissue: *California* (A.B. 1251), *Florida* (Fla. H.B. 1237); which could have the effect of unintentionally banning research using cloned cells or tissue: *South Carolina* (H.B. 3617 ♣ 16-17-745(B)), *New York* (A.B. 5383). See, NBAC Report pg. 104 for cite list.

<sup>25</sup>NBAC Report pg. 104.

merce Committee where it was referred.<sup>26</sup>

Another early bill, S. 368, later amended and reintroduced as S. 1601 and sponsored by Sen. Christopher Bond (R-Mo.), had essentially the same purpose as the House bill mentioned above. The final bill is designed to prohibit any person or entity from using SCNT technology for the purpose of cloning a human as well as prohibiting importation of cloned embryos created by the same technology.<sup>27</sup> According to the bill's summary, it was drafted with the intention of protecting scientific research in mind.<sup>28</sup> In a press release Bond commented that "[H]uman cloning has no place in the world of legitimate scientific research," that mankind is "not prepared from an ethical or moral standpoint" for this technology and that Congress had the responsibility of enacting "a permanent ban on human cloning."<sup>29</sup>

Some of the same criticisms that had been expressed in relation to state legislative proposals were echoed in response to the Bond bill. Of most concern is that due to the broad and ill defined language found in the bill it prohibits practices already well established and accepted and would have the effect of prohibiting promising areas of research.<sup>30</sup> The "assertions that it protects biomedical research are ludicrous" said Sean Tipton of the American Society for

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<sup>26</sup> *Research Oversight: FDA May Assert Its Authority to Regulate Human Cloning Technology Under Biologic Product Regs.*, The Blue Sheet (F-D-C- Reports, Inc.) Volume 41, Issue 2, January 14, 1998

<sup>27</sup> *Lott Promises Vote on Cloning Ban Before Senate's President's Day Recess*, BNA Washington Insider (Bur. of Nat'l. Affairs Inc.) February 4, 1998.

<sup>28</sup> *Id.*

<sup>29</sup> *Senate Democrats Block Immediate Vote on Bond Bill to Ban Human Cloning*, BNA Washington Insider (Bur. of Nat'l. Affairs Inc.) February 6, 1998.

<sup>30</sup> *FDA Affirms Authority to Regulate Human Cloning Involving Nuclear Transfer*, BNA Washington Insider (Bur. of Nat'l Affairs Inc.) January 21, 1998.

Reproductive Medicine (ASRM).<sup>31</sup> The Biotechnology Industry Organization (BIO) submitted a statement declaring that “biomedical research into deadly and disabling diseases is far too important to rush to enact legislation [such as the Bond bill] which would unequivocally undermine promising research and therapies.”<sup>32</sup> Restrictions on research such as those found in this bill may prevent possible cures for cancer, cystic fibrosis, heart disease, diabetes and other disabling conditions.<sup>33</sup>

In response to these concerns, Senate Democrats submitted their own proposal, S. 1602. This bill proposes a 10 year moratorium on human cloning activities and contains much more precise language concerning the activities affected. In addition, it would mandate that at the end of the 10 year moratorium, the issues involved would be revisited in order to evaluate whether a new regulatory regime was indicated. This bill is much more responsive to the concerns of industry, health care workers and academics and follows the recommendations issued by the NBAC. Sen. Dianne Feinstein (D-Calif.), one of the sponsors of the bill, emphasized the “enormous harm” that would be done by passage of an uninformed bill in this matter and urged congress to carefully consider and seek a real understanding of the technical issues involved.<sup>34</sup> To date, neither of these Senate bills has been enacted.

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<sup>31</sup>Sharon Schmickle, *Capital Hill Struggles to Set Proper Limits on Science and Human Ingenuity*, Minneapolis Star Tribune, February 9, 1998.

<sup>32</sup>*Id.*

<sup>33</sup>*Ethical Issues Deserve More Attention in Context of Cloning Legislation, Panel Told*, BNA Washington Insider (Bur. of Nat'l. Affairs Inc.) February 13, 1998.

<sup>34</sup>*See, infra*, note 29.

## V.

### HUMAN CLONING AND FDA REGULATION

#### A.

##### EXISTING GUIDELINES

The FDA's involvement in this matter was triggered by the announcement of Dr. Richard Seed, a physicist, on January 7, 1998, that he intended to begin using SCNT technology to begin human cloning operations for sterile couples at a Chicago clinic. As no regulation in this area was believed to exist at the time, the announcement caused panic in many circles. Filling this apparent regulatory vacuum the FDA, in a statement issued a few days later, announced that it had the authority to regulate cloning technology as a biological product.<sup>35</sup> The acting FDA commissioner Michael Friedman made it clear that the FDA was prepared to take all actions available to stop "unauthorized" human cloning attempts.<sup>36</sup>

The agency claimed authority to regulate this activity under section 351 of the Public Health Services Act.<sup>37</sup> According to agency and industry

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<sup>35</sup>*FDA Has Authority to Regulate Cloning Technology as Biologic Product, Agency States After Chicago Physicist Seed Announces Plans For Human Cloning Clinic*, Health News Daily (F-D-C Reports, Inc.) Volume 10, Issue 8, January 13, 1998.

<sup>36</sup>News Services, *No Human Cloning Without Approval, FDA Says*, Minneapolis Star Tribune, January 20, 1998.

<sup>37</sup>42 U.S.C. 262 et. seq. See eg., The Food and Drug Administration, *Proposed Approach to Regulation of Cellular and Tissue-Based Products* (last modified February 28, 1997) <<http://www.fda.gov/cber/cberftp.html>> (Proposed Regs.)

sources,<sup>38</sup> regulatory framework for the regulation of cellular and tissue-based products (RCTP) proposed in February of 1997 would give FDA the appropriate tools to oversee the use and development of this new technology.<sup>39</sup> These regulations were initially proposed in an attempt to provide a unified framework for the oversight of cellular and tissue-based products, replacing the fragmented approach to these articles previously applied.<sup>40</sup> One of the stated goals of the RCTP was to ensure the clinical safety and effectiveness of tissues and cells that are highly processed.<sup>41</sup> It is clear however, that in drafting the regulations proposed, the topic of human cloning had not been considered.

Agency officials sought to bring human cloning by SCNT under the rubric of the RCTP, through a clause in the proposed regulations which stated that, “[C]ells or tissues that are *more-than-minimally manipulated*” would be subject to the requirements of the regulations.<sup>42</sup> According to industry sources, “proposal[s] to clone humans using nuclear transfer technology [propose] much more than minimal manipulation” of human cells.<sup>43</sup> Further, based on the same information given earlier, FDA has determined that the type of manipulations involved in cloning a human being using SCNT technology poses “serious health and safety issues” for the developing fetus and its mother.<sup>44</sup> According to the

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<sup>38</sup>*FDA Asserts Authority to Regulate Human Cloning: An Out For Industry Wary of Legislative Ban?*, The Pink Sheet (F-D-C Reports, Inc.) Volume 60, Issue 3, January 19, 1998; Lisa Seachrist, *BIO Says Human Cloning Falls Under FDA’s Purview*, BIOWORLD Today, Vol. 9, No. 9, January 15, 1998.

<sup>39</sup>Proposed Approach to Regulation of Cellular and Tissue-Based Products, 62 Fed. Reg. 9721 (1997) (to be codified at 21 C.F.R. Chapter I); Proposed Regs. *Infra* at note 37.

<sup>40</sup>Proposed Regs. *Infra.* at note 37.

<sup>41</sup>*Id.*

<sup>42</sup>*Id.*

<sup>43</sup>*See, Infra.* note 38.

<sup>44</sup>Rick Weiss, *Human Clone Research Will be Regulated; FDA Asserts it Has Authority to Regulate Attempts at Human Cloning*, The Washington Post, January 20, 1998.

FDA then, these factors indicate that any individual wishing to attempt to clone a human using SCNT technology would have to submit to the requirements mandated by the aforementioned regulations.

At first, the formal procedures followed by these individuals would include having to file an “investigational new drug” application (IND).<sup>45</sup> This would include having to demonstrate that the procedure being planned does not pose an unreasonable risk of harm to potential human subjects. In evaluating an IND the agency would require pre-clinical data including any gained from trial programs and models involving animals to ensure safety and efficacy. Once safe methods have been demonstrated and accepted though, FDA would seek to establish manufacturing and product standards ensuring safety and efficacy for industry wide application in SCNT cloning processes. Under this latter regime, those wishing to clone a human being would be “subject to processing controls that generally would cover chemistry, manufacturing and controls (CMC’s) and to premarket requirements for determination of safety and effectiveness.”<sup>46</sup> Thus, once such standards have been established, those wishing to engage in the practice of human cloning would presumably have to adhere to standards for combining a somatic cell with an egg for the purpose of creating a human clone and for the content or makeup of the product of these two entities itself.

B.

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<sup>45</sup>Washington Post *Infra.* at note 44; Proposed Regs. *Infra.* at note 37.

<sup>46</sup>Proposed Regs. *Infra.* at note 36.

## ANALYSIS OF REGULATION UNDER EXISTING GUIDELINES

As an interim measure, FDA's proposal to regulate human cloning technology under the cellular and tissue-based based products regulations is exactly what the situation calls for. Great urgency was infused into the quest to enact some kind of regulatory scheme by Dr. Seed's announcement. In addition, most legislative proposals advanced seem plagued by a lack of knowledge of many of the issues involved. By filling the regulatory void, FDA not only brings uniformity to this area, but insures that lawmakers no longer have to worry about the prospects of immediate unconstrained activity in the area of human cloning. After all, given the current development in the field, it is highly improbable that safety and efficacy could be demonstrated in the near future, making approval of any IND application unlikely for some time. FDA's announcement therefore, achieved two short term goals. First, it guaranteed that at a minimum, public health and safety concerns would not be neglected in a rush to institute this new technology. Second, it gave lawmakers a chance to slow down, better educate themselves on the matters under consideration and engage in a more informed analysis before demanding enactment of any new congressional edicts.

Industry has demonstrated widespread support for this interim approach. Carl Feldbaum, president of BIO, stated that the approach gave lawmakers "breathing space" to consider responsible legislation while at the same time protecting biomedical research.<sup>47</sup> A spokesman for the Pharmaceutical Re-

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<sup>47</sup> See, *Infra.* note 38.



search Manufacturers Association (PhRMA) commented that “lawmakers are moving too fast.”<sup>48</sup> This is an “area that needs much more debate than the senate has had to date” and FDA has the “expertise to look at the immediate concerns.”<sup>49</sup> Support in academia is strong as well. According to a statement from the Association of American Medical Colleges (AAMC) a “self imposed five year moratorium on human cloning coupled with [FDA] oversight should effectively safeguard the public while fostering medical progress.”<sup>50</sup> Even those in favor of a perpetual ban on human cloning activities could save their strength for the battle which lay ahead since any authorized short term cloning activities were highly improbable.

Taken as a whole, the regulatory framework proposed by FDA would address many of the long term issues raised in the debate discussed earlier as well. As mentioned in preceding paragraphs, it would at a minimum require that the safety and efficacy of any cloning procedure be demonstrated before any human clone was allowed to be created using SCNT methods, thereby allaying public health concerns. The proposed framework would not, however, foreclose the possibility of future application of the technology. Thus, if at some point in the future the technology were to become highly enough refined, it could be made available. In addition, Friedman has stressed FDA’s commitment to “balance” in the regulation of this technology so that research and development won’t be unnecessarily inhibited.<sup>51</sup> By requiring safety in application without

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<sup>48</sup> *See, infra.* note 29.

<sup>49</sup> *See, infra.* note 31.

<sup>50</sup> *GOP Bill Banning Human Cloning Put On Hold as Lawmakers Struggle With Legislation*, Transplant News (Information Access Co.) Vol. 8, No. 3, February 13, 1998.

<sup>51</sup> *Human Cloning Subject to FDA Jurisdiction as a Biological Product Agency Says*, The

interfering with legitimate research while also creating a regulatory pathway for potential future approval, this scheme would address many of the fears enunciated by the scientific, regulatory and health care communities, including those in industry.

The RCTP also provides a balancing mechanism to be used when contemplating constitutional considerations. Counter to Professor Robertson's suggestion that the burden of proof be placed on those who oppose the availability of cloning technology to prove harm, the proposed regulations require the aforementioned showing of safety on the part of those who would utilize the technology. Despite this fact, once shown to be safe, it appears that this avenue of procreation would be made available to any who could afford it. At that point, this "constitutional freedom" would be as available as other currently used fertility methods. The legal burden imposed would simply mitigate in favor of public health concerns and, some would argue, the constitutional liberties of the developing fetus. Under this analysis, it appears that at least the main theme, if not the particular details, of Robertson's argument for a weighing of factors in order to preserve liberties is retained and that SCNT cloning of human beings would be permitted lacking "substantial harm."

As for addressing moral/ethical concerns the current regulatory proposal is not quite as strong. In its present form, it would seem the only argument the agency could make affecting the final use of the clone would be based on safety and health concerns of the clone itself. By arguing that, harvesting clones,

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Gray Sheet (F-D-C Reports Inc.) Vol. 24, Is. 3, January 19, 1998.

either for their organs for transplantation into others or to create some type of permanent “labor” or other such class, inherently endangers the health of the clone, the agency might be able to require those producing clones to prove that these clones are not being manufactured for such purposes before such facilities are licensed. While this seems to be the strongest weapon in the Agency’s arsenal along this front, the success this argument would enjoy is unknown. Along the same lines, this regulatory scheme doesn’t even touch upon the religious concerns expressed. In order to make up for these deficiencies Agency officials have suggested public hearings on the issue of human cloning.<sup>52</sup> According to these officials the hearings would “be done in the open [so that] everyone has a say and we face our fears in public and discuss them.”<sup>53</sup>

While hearings would certainly be a necessary step towards implementation of FDA’s plans for long term application of these regulation to SCNT human cloning technology, they are not enough to save the proposal. It is of paramount importance to remember that when these regulations had been proposed, the idea of cloning an adult human was still in the realm of science fiction. Thus they were fashioned without many of the concerns now being expressed considered at all. While on research and development fronts the process of human cloning can in it’s technological features be easily analogized to the other biotechnologies covered by these regulations, along the moral/ethical and religious fronts the comparison is woefully inadequate. These moral/ethical and religious questions cannot be answered in a lab.

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<sup>52</sup> *See, Infra.* note 44.

<sup>53</sup> *Id.*

To many, this new capability impacts on the very meaning of our humanity. Before unquestioned authority to regulate this technology is handed over to the FDA, the democratic process, as it operates through the peoples representatives in Congress, should specifically consider all the implications of any proposed regulatory regime. As a result, while the FDA's proposal is an excellent short term solution, and its effect on many of the issues considered is quite desirable, the fact that many other important concerns have not been, and cannot appropriately be, addressed by the Agency indicates that a new regulatory regime might be necessitated.

C.

#### FRAMEWORK FOR A NEW PROPOSAL

A favorable feature of any type of federal regulation in this area is that it would supply uniform standards to follow throughout the country. This uniformity “would relieve the need to rely on the cooperation of diverse medical and scientific societies, or the actions of diverse [institutional review boards], to achieve [policy objectives]”<sup>54</sup> and would facilitate researchers in their attempts to clearly identify the demarcation lines of permitted activities. Despite the diminution in reliance upon such sources to achieve policy objectives, by instituting a federally mandated regime, medical and scientific societies would also become strengthened and unified in this area and so be better able to lend their well informed voice to the nation in advising where lines should be drawn

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<sup>54</sup>NBAC Report.

and the advantages of this technology to all individuals. Additionally, it would facilitate the development of interstate commerce in this area prevent “forum shopping” brought on by competition between the states designed to attract this type of industry by enacting weak, if any, regulation regarding the use of this technology. Such competition would be dangerous since this technology, as stated above, is open to seriously questionable uses.

For the short term, regulation in this area should be left in the hands of the FDA. This should be considered purely an interim measure until Congress has considered and passed new legislation. In arriving at this legislation, Congress should conduct open hearings on the issues involved allowing widespread participation. The hearings should be informed by the NBAC report as it was arrived at through the free exchange of ideas by individuals from a vast array specialties covering religion, science, industry and government. Beyond this, the following framework provides a starting point for discussion.

#### MODEL LEGISLATION FOR THE REGULATION OF HUMAN CLONING

(1) All attempts to clone a human being using somatic cell nuclear transplantation techniques shall be governed by this statute.

(a) The term “Human being” shall refer only to individuals, freely functional or not, existing outside the womb.

(b) Any and all fetal or embryonic research or other issues concerning treatment of a fetus or embryo, will be covered by laws already composed for those purposes.

(2) Any individual, entity or institution desiring to engage in human cloning activities must obtain a license for such from the Food and Drug Administration (FDA).

(3) In regulating the human cloning process, the FDA will treat it as involving “more than minimally manipulated” cells and thus needing to satisfy

all the requirement prescribed for such entities under it's Cellular and Tissue-Based Products regulations. This will include initially the need to undergo the IND application process and the demonstration that any proposed methods of producing an embryo are effective and safe for both the developing fetus and the mother in which the embryo is to be implanted. Once it becomes possible to establish industry wide standards, FDA will establish processing controls and other pre-birth requirements for determination of safety and effectiveness.

(a) The FDA may, from time to time and as it sees fit, prescribe any additional requirements for the issuance of such a license as long as such requirements do not contradict the requirements set forth in this section or any other section dealing with the regulation of human fetal or embryonic research and treatment.

(b) In addition to the requirements stated above and any additional requirements established by the FDA, in order to obtain and/or keep a license the individual, entity or institution in question must;

(i) Demonstrate that they intend to engage in cloning activities for the sole purpose of assisting people to have children, intended to be reared as children with the full compliment of human rights accorded other non-cloned individuals;

(ii) Demonstrate their individual proficiency in the use of somatic cell nuclear transfer technology for the purpose of cloning a human;

(iii) Demonstrate compliance with all rules, regulations and laws concerning research and treatment of the human fetus and embryo;

(iv) File complete records of each such attempt which must include whether such attempt was a success or failure, the actual product of said attempt, the identity of the DNA donor and the identity of the clones designated parents;

(v) Abide by any and all other regulations governing the practice of reproductive medicine.

(4) Any research directed at the cloning of a human being using somatic cell nuclear transplantation must be done with the goal of producing healthy children for rearing.

(a) Any research conducted using human beings or their embryos must conform to accepted human medical trial protocols.

(b) A human being CANNOT be cloned simply for the sake of pure research.

(5) It will be a crime carrying up to --- years of imprisonment and up to a ---- dollar fine to commit or attempt to commit any of the following acts;

(a) Engage in the practice of human cloning without obtaining, and complying with all requirements for obtaining, a license;

(b) Knowingly violate any of the rules or regulations authorized under this section;

(c) Perform, participate in or aid in any material way the act of cloning a human being when the individual in question knows or has reason to

know that either the care giver, the donor or the respective parents of the clone are engaging in this activity

- (i) for the eugenic purpose of race selection;
- (ii) for the purpose of harvesting the organs of the clone for transplantation into another individual;
- (iii)

for the creation of a human being in a lab outside of a human womb.

This proposal is meant only to be a starting point. I have great confidence in FDA's ability to regulate in this area but realize that there are other well reasoned positions. In particular, this proposal is not likely to satisfy those who oppose cloning on religious or certain other moral grounds. I have tried to compromise in order to include as many interests and objections as possible. I hope that it may be helpful.

## **VI. CONCLUSION**

Given the current state of human cloning technology using somatic cell nuclear transfer techniques, it is likely to be quite some time before a clone of a fully formed, freely function human being can be created. Nonetheless, given the claims by certain individuals that they will begin attempting to put this technology to use in the near future, some immediate government oversight is necessary. In the short term, the FDA can regulate this activity under its proposed regulations on cellular and tissue-based products. This seems a very good interim approach. In the long run though, while FDA may be the appropriate

entity to administer any regulatory regime, Congress is going to have to face the issue head on and determine what the appropriate framework is. SCNT human cloning technology holds great promise for mankind, but is also accompanied by grave concerns. By addressing these issues in a careful and thoughtful manner now, we hold open the promise this technology holds for us in the future.